

Dec. 20, 1995 K963825

510(k) SUMMARY OF INFORMATION:

SUBMITTER: United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06856
(203) 845-1000

CONTACT PERSON: Curtis Raymond

DATE PREPARED: December 18, 1996

CLASSIFICATION NAME: Manual Surgical Instrument for general use

COMMON NAME: Biopsy Device

PROPRIETARY NAME: Auto Suture* ABBI* Breast Biopsy System

PREDICATE DEVICE: Bard® Biopty® Instrument Biopsy-Cut® Needle
(K871390).

DEVICE DESCRIPTION: Both the Auto Suture* ABBI* Breast Biopsy System,
and Bard® Biopty® Instrument Biopsy-Cut® Needle
(K871390) are indicated for obtaining soft tissue
samples under imaging control.

INTENDED USE: Like the Bard Biopsy Needle (K871390), the Auto
Suture* ABBI* Breast Biopsy System is intended for
obtaining biopsies from breast tissues for diagnostic
purposes. The device is not intended for
therapeutic excision of tissue.

MATERIALS: All component materials of the Auto Suture* ABBI*
Breast Biopsy System are comprised of materials
which are in accordance with ISO Standard #109931.

PERFORMANCE: Both the Auto Suture* Auto Suture* ABBI* Breast
Biopsy System and the Bard Biopsy Needle (K871390)
are effective in removing a sample of tissue for biopsy.